[Submitting counsel on signature page]

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

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| In re LIDODERM ANTITRUST LITIGATION | MDL Docket No. 14-md-02521-WHO |
| This Document Relates to:<br><br>All Actions | **DEFENDANTS' MOTION FOR RECONSIDERATION REGARDING PROOF NECESSARY TO ESTABLISH CAUSATION**<br><br>Judge: Hon. William H. Orrick<br>Date: January 29, 2018<br>Time: 2:00 pm<br>Courtroom: 2, 17th floor |

**NOTICE OF MOTION AND MOTION**

**TO ALL PARTIES AND THEIR COUNSEL OF RECORD**:

**PLEASE TAKE NOTICE** that on January 29, 2018, at 2:00 p.m., or as soon thereafter as this matter may be heard, at the courtroom of the Honorable William H. Orrick, Courtroom 2, 17th floor, United States District Court, 450 Golden Gate Avenue, San Francisco, California, Defendants Actavis, Inc., Watson Laboratories, Inc. and Actavis plc (collectively "Watson") and Endo Pharmaceuticals Inc. ("Endo"; together with Watson, "Defendants") shall and do hereby move this Court for an order reconsidering so much of the Court's November 3, 2017 Order (ECF 900) as concerns the standard of proof necessary to establish causation at trial. This motion is made pursuant to Local Rule 7-9 and the Court's leave granted at the December 18, 2017 hearing (*see* ECF 936 at 1).

Defendants base this motion on this Notice of Motion and Motion, the accompanying Memorandum of Points and Authorities, the concurrently filed Declaration of Daniel B. Asimow and its exhibits, the pleadings and other filings in this action, such arguments and authorities as may be presented at or before the hearing, and any other matters the Court may consider.

## INTRODUCTION

Plaintiffs contend they were worse off because of the settlement—i.e., that it caused them injury. Injury causation is a critical element of their case, and one which they must prove by a preponderance of the evidence. Thus, if in pursuing their "at-risk" launch theory, Plaintiffs fail to prove—by a preponderance—that Watson ultimately would have invalidated Endo's '529 patent and been able to keep its generic product on the market for a *longer* period than it was on the market under the settlement, then Plaintiffs will not have proven injury causation. "Some evidence" that Watson "could have" invalidated the patent does not suffice: it does not establish by a preponderance of the evidence that the settlement caused Plaintiffs injury they would not otherwise have experienced. Only by proving that Watson would have stayed on the market (i.e., ultimately won the patent case) can Plaintiffs prove *longer* generic availability than under the settlement, and thus the overcharge damages Plaintiffs seek to recover.

The Court has held that Plaintiffs need not "prove *in this case* that Watson *would have* won its patent litigations" but instead need only "show 'some evidence' that Watson could have won." ECF 900 ("Order") at 8–9. The Court explained that it intended by this to lay out "what the causation standard of proof is for trial, not for summary judgment purposes," but permitted Defendants to move for reconsideration. ECF 943 at 24:9-15.

Defendants respectfully submit that this injury-causation standard of proof conflicts with well-settled antitrust law, ABA model jury instructions, and the only two federal courts of appeal to have decided the issue in the reverse-payment context. To show injury causation under their at-risk causation theory, Plaintiffs must prove by a preponderance that Watson *would* have prevailed on invalidity. And while the preponderance standard does not require certainty—it simply requires that the jury be convinced that a proposition is more likely true than not—the formulation of "some evidence" that an event "could have" happened erroneously lowers that bar.

Moreover, although the Court has expressed concerns about the efficiency of trying the patent case within the antitrust case, Order at 8, applying the standard used in past reverse payment cases will not require a full trial within a trial. For instance, the parties may offer expert testimony on the likely outcome of the patent case, as Plaintiffs prepared to do here all along. Their expert,

Mr. Adelman, says that the *entire* litigation record—not merely some evidence—shows a 90% likelihood Watson *would have* won. No doubt Plaintiffs will seek to rely also on evidence of the parties' perceptions of the case; the settlement itself; and the import of the alleged payments. But it would be incorrect as a matter of law to try this case with a framework that allows the Plaintiffs to recover simply on the basis of "some evidence" that the settlement "could have" caused them harm. That would allow a finding of liability even when the weight of the evidence shows, and the jury believes, that it is more likely than not the Defendants' settlement caused Plaintiffs no harm. This, in turn, would create an appellate issue that would permeate the entirety of any liability verdict. Defendants respectfully request that the Court reconsider this aspect of its summary judgment ruling.

## ARGUMENT

### A. Plaintiffs in a Private Antitrust Damages Action Must Establish Causation by a Preponderance of the Evidence.

Under Section 4 of the Clayton Act, "any person who shall be injured in his business or property *by reason of* anything forbidden in the antitrust laws may sue therefor." 15 U.S.C. § 15(a) (emphasis added). Causation is thus an essential element to establish liability. *Associated General Contractors of California, Inc. v. California State Council of Carpenters*, 459 U.S. 519, 535–37 (1983); *Handgards, Inc. v. Ethicon, Inc.*, 743 F.2d 1282, 1295 (9th Cir. 1984). The plaintiff must demonstrate a causal connection between the antitrust violation and the plaintiff's injury with "reasonable probability." *Northwest Publ'ns, Inc. v. Crumb*, 752 F.2d 473, 476 (9th Cir. 1985). And that causation burden is not lowered even where a defendant's conduct would be deemed anticompetitive. For instance, in *Northwest Publications*, even though the defendant violated the Sherman Act through *per se* illegal resale price maintenance clauses, other circumstances had precluded the distributor plaintiffs from raising their prices; the distributors thus failed to show injury causation, because "[s]ome other, entirely legal, competitive market force" was at play. *Id.* at 474–76; *see also Argus Inc. v. Eastman Kodak Co.*, 801 F.2d 38, 40, 41–42 (2d Cir. 1986) (because "an essential element in plaintiffs' claim is that the injuries alleged would not have occurred *but for* Kodak's antitrust violation," affirming judgment against plaintiffs despite that Kodak was

collaterally estopped from denying that it had violated the Sherman Act).

As an essential element in any civil case, causation must be established by the plaintiff by a preponderance of the evidence. *See Herman & MacLean v. Huddleston*, 459 U.S. 375, 387-90 (1983) (preponderance standard applies to "violations of other federal statutes such as the antitrust or civil rights laws"); *see also, e.g., Los Angeles Mem'l Coliseum Comm'n v. Nat'l Football League*, 791 F.2d 1356, 1365 (9th Cir. 1986) (jury instructed that plaintiffs must meet "their burden of proving, by a preponderance of the evidence, 'that the injury was the result of a restriction in competition'"). The preponderance standard is more relaxed than the clear and convincing burden of proof that applies "where particularly important individual interests or rights are at stake." *Herman & MacLean*, 459 U.S. at 389. (Although it was the latter, more stringent burden that Watson bore in attempting to invalidate the '529 patent.[1]) The preponderance standard "allows both parties to share the risk of error in roughly equal fashion," whereas "[a]ny other standard expresses a preference for one side's interests." *Id.* at 390; *see also Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1058, 1060 (8th Cir. 2000) (preponderance standard for attempted monopolization); *Virginia Vermiculite, Ltd. v. W.R. Grace & Co.—Conn.*, 144 F. Supp. 2d 558, 589 (W.D. Va. 2001) ("plaintiff in a civil action bears the burden of proving an antitrust violation, such as a conspiracy to monopolize, by a preponderance of the evidence").

The same principle is embodied in the ABA's model antitrust jury instructions: the plaintiff is required to prove that its injury "was the direct result or likely consequence of the unlawful acts of defendant," and "bear[] the burden of proving damages by a preponderance of the evidence . . . . If [the jury] find[s] that plaintiff's alleged injuries were caused by factors other than defendant's alleged antitrust violation, then [it] must return a verdict for defendant." ABA Model Instr. 6.B.4 (2016). Whatever leniencies are sometimes afforded in proving the precise *quantum* of damages, those do not relax the preponderance burden for proving causation of harm in the first instance. *See, e.g., Northwest Publ'ns*, 752 F.2d at 477 ("The burden on [antitrust plaintiffs] to show causation is more stringent than the burden to prove the amount of damages.").

[1] *See Microsoft Corp. v. i4i Limited Partnership*, 564 U.S. 91, 95 (2011) (A patent "invalidity defense [must] be proved by clear and convincing evidence.").

There is no authority establishing a lower standard of proof for the essential element of injury causation in private antitrust actions. Nor is there any authority for allowing the jury to rest causation on only a subset of the evidence, or to find simply that a particular causation obstacle "could have" been surmounted, rather than that it actually "would have" been. *See, e.g.*, *Williams v. Boorstin*, 663 F.2d 109, 115 (D.C. Cir. 1980) ("What 'could have been' is never alone a sufficient foundation for a finding of what really 'was'[.]"). Instead, "[t]he trier of fact must be able to ascertain causal antitrust injury without engaging in speculation." *Catlin v. Washington Energy Co.*, 791 F.2d 1343, 1347 (9th Cir. 1986) (internal quotation marks omitted).

**B. Courts in Reverse-Payment Cases Have Applied a Preponderance-of-the-Evidence Standard for Injury Causation.**

Consistent with this black-letter law, the only two federal appellate courts to consider causation post-*Actavis* have treated the outcome of the underlying patent litigation no differently than any other causation hurdle and required plaintiffs to show it more likely than not that the would-be generic entrant would have won the patent case.

In *Wellbutrin*, the plaintiffs pointed to the same indicia to which Plaintiffs point here to show that the would-be generic entrant could have won: the generic had certified its positions in a paragraph IV letter, and the brand had made an alleged payment. In fact, the "evidence in the record that sp[oke] to the possible outcomes of the" litigation indicated that the generic had "a 20% chance of winning the suit." 868 F.3d 132, 169 (3d Cir. 2017). Notwithstanding this "some evidence" that the would-be entrant "could have won," the Third Circuit affirmed judgment for the defendants because "no reasonable jury could conclude that [the would-be entrant] ***would have been more likely than not*** to prevail." *Id.* (emphasis added).

In *Nexium*, the First Circuit found the district court decision in *Wellbutrin* "persuasive," and affirmed a defense judgment where "the plaintiffs did not present [] evidence that the brand-name's patents ***would have*** been declared invalid or that an at-risk launch ***would not have*** infringed the patents." 842 F.3d 34, 63 (1st Cir. 2016) (emphases added). "Upon the conclusion of the plaintiffs' case in chief, the district court saw no evidence that would allow the plaintiffs to overcome the likelihood that [the brand's] patents, not its reverse payment to [the generic], were the bar to a

generic launch." *Id.*; *accord Apotex, Inc. v. Cephalon, Inc.*, 255 F. Supp. 3d 604, 613 (E.D. Pa. 2017) ("[T]he only two courts to have considered the elements of an at-risk launch theory of causation have both held that a plaintiff must demonstrate that a generic defendant's decision to launch at-risk *would be 'lawful'*—meaning that the brand company's patent is invalid or not infringed by the generic product launched at-risk") (emphasis added).

*Nexium*'s reference to "some evidence" came in the context of sustaining judgment as a matter of law under Rule 50: Plaintiffs needed some evidence of invalidity before being "allow[ed] . . . to pursue an at-risk launch theory" to verdict. 842 F.3d at 63. That is why Plaintiffs have previously described *Nexium* (and *Wellbutrin*) as "st[anding] for the proposition that *to survive summary judgment* Plaintiffs must offer some evidence that the generic would have won the patent litigation." ECF No. 819, at 20 (emphasis supplied). At the *Nexium* trial, despite that the jury had found for the plaintiffs on market power, a large and unexplained payment, and anticompetitive effects, there was insufficient causation evidence: the *Nexium* plaintiffs' "evidence regarding the assessment of risk in the context of showing an antitrust violation under the *Actavis* rule of reason framework" did not get them across the threshold on the separate question of "causation." *Apotex*, 255 F. Supp. 3d at 613 (describing *Nexium*).

*Cipro* did not set out a different rule for causation but, instead, merely rejected patent validity as a trump card in the rule of reason: "validity will not *automatically* demonstrate an agreement was procompetitive." 348 P.3d 845, 870-71 (Cal. 2015) (emphasis supplied); Order at 7. *Cipro* did not there address injury causation, nor could it have: its central holding was that "[p]arties illegally restrain trade when they privately agree to substitute consensual monopoly in place of potential competition *that would have followed a finding of invalidity or noninfringement*." *Id.* at 851 (emphasis supplied). Plaintiffs agree that "*Cipro* principally addresses the evidence necessary to prove an antitrust violation, ***not causation***." ECF 819 at 26 (emphasis supplied); Order at 17 ("the *Cipro* court was not analyzing causation"). Moreover, in *Cipro*'s view, "the relevant comparison is with the average level of competition that *would have* obtained absent settlement, i.e., if the parties had litigated validity/invalidity and infringement/noninfringement to a judicial determination." *Id.* at 864 (emphasis supplied). *Cipro* did not adopt a "some evidence"/"could

have" standard.[2]

This Court also cited *In re Opana ER*, 162 F. Supp. 3d 704, 720 (N.D. Ill. 2016), and *In re Aggrenox*, 94 F. Supp. 3d 224, 241 (D. Conn. 2015). Order at 8. These motion to dismiss rulings could not, by their terms, have decided what standard a jury would apply at trial. As the First Circuit recognized in *Nexium*, such decisions are "inapposite" to determining the standard of proof at trial. 842 F.3d at 62-63 (rejecting citation to "cases [that] evaluated allegations of antitrust injury at the Rule 12(b)(6) stage"). And both decisions predated *Nexium* and *Wellbutrin*, at a time when, as the *Aggrenox* court noted in certifying its order for interlocutory review, "no federal court of appeals ha[d] yet opined on the question." 2015 WL 4459607, *11.

This Court also noted that the *Actavis* opinion did not "require[] (or even suggest[])" private antitrust plaintiffs would need to prove that the generic company would have won the patent litigation. Order at 8. Respectfully, there is no reason to expect *Actavis* to have reached that issue. *Actavis* simply reversed the grant of a motion to dismiss an FTC complaint—it had no need to set out a standard of proof for trial, much less in a private purchaser case. The court's focus in *Actavis* was on how to factor patent life into the rule of reason—specifically, on "determining the 'scope of the patent monopoly'—and consequently antitrust law immunity—that is conferred by a patent," 133 S. Ct. 2223, 2231 (2013)—rather than on the question of injury causation in a damages case.

As such, *Actavis*'s elliptical comment that "it is normally not necessary to litigate patent validity to answer the antitrust question," *id.* at 2236, did not lower the standard of proof for injury causation. The most reasonable reading of *Actavis* in this respect is simply that "litigat[ing] patent validity" may not be necessary in the context of an FTC action, where causation is not an element of the plaintiff's claim. ECF 854 at 2. A private purchaser seeking damages stands in different shoes, and must prove injury causation apart from the rule of reason. *See* 15 U.S.C. § 15.

[2] Far from endorsing such a standard, *Cipro* advocated a "probabilistic" approach. Plaintiffs here, of course, do not advocate that approach, under which the question would be whether Watson was more than 62% likely to prevail in its challenge to the '529 patent—because the licensed entry date here (September 15, 2013) was only 38% of the way into the patent's expiry (October 27, 2015) at the time of settlement (May 28, 2012). *See* 348 P.3d at 864. Such an approach, moreover, would preclude reliance on Plaintiffs' second theory, alternative settlement. *Id.* at 864 n.10.

This distinction was an important part of the briefing in *Actavis* itself, as the parties debated whether, without a "scope of the patent" test, challenges to reverse payments would necessarily require a trial of the patent claims resolved by the settlement. In arguing "no," the FTC distinguished its cases, brought pursuant to Section 5 of the FTC Act, from private suits seeking damages under the Section 4 of the Clayton Act, 15 U.S.C. § 15:

> [T]he plaintiff [in a private suit for damages] can collect damages *only* by proving economic harm, which requires evidence as to the sequence of events that would likely have occurred if no reverse payment had been made.

Ex. 1 at 14 (emphasis added). "That issue" was not presented in *Actavis* "because the FTC [sought] only declaratory and prospective injunctive relief." Ex. 2 at 55 n.11. In adopting a contrary interpretation, this Court is thus not only declining to follow the only existing federal appellate authority—i.e., *Nexium* and *Wellbutrin* (Order at 6)—but also the position the FTC took in *Actavis* itself.

As the FTC explained further as *amicus* in *Nexium*, while both the FTC and purchaser plaintiffs must prove anticompetitive effects, purchasers alone "must satisfy the additional burdens" of proving that they "suffered an injury-in-fact." Ex. 3 at 9-10. "Th[e] showing of injury-in-fact is analytically separate from . . . the showing of anticompetitive effects," and "[t]he distinction . . . is particularly important in the context of a reverse-payment agreement." *Id.* at 13-14, 16.[3] If "[u]nder *Actavis*, the relevant anticompetitive harm from a large and unjustified reverse payment is that it prevent[s] the *risk* of competition," *id.* at 16, that "anticompetitive harm" does not by itself cause injury to purchasers. To establish damages, the Plaintiffs must prove "actual injury—such as an overcharge to a specific plaintiff." *Id.* at 18.[4] Here, unless Watson *would have* prevailed in its challenge to the '529 patent, Plaintiffs have no overcharge damages—a finding that Watson *could have* prevailed simply does not establish injury causation.

[3] Consistent with this distinction, the FTC cast *Cipro* and *Aggrenox* as speaking to anticompetitive harm generally, rather than to injury causation for damages purposes. Ex. 3 at 20.

[4] "[I]f it were otherwise, the injury-in-fact inquiry would itself be largely redundant: Establishing an actual price increase would simultaneously show an anticompetitive effect and an overcharge injury." Ex. 3 at 14.

Most important for purposes of this motion, no court has read *Actavis* as requiring that the jury be charged with a "some evidence"/"could have" standard as to patent validity. Indeed, this Court's holding that the "large and unexplained . . . reverse-settlement payment" is "not sufficient on its own," Order at 57, suggests that the Court does not intend to wholly eliminate the causation element in a private case. But the "some evidence" standard would do just that. As embraced by Plaintiffs in their proposed jury instructions, it would allow injury causation to be established with evidence that would not be sufficient to establish an element of a claim in any other private civil litigation. Plaintiffs should be required, like all civil litigants, to prove their case by a preponderance of the evidence. No more, no less.

### C. Plaintiffs Cannot Show Injury Causation on an At-Risk Launch Theory Unless Watson's Challenge to Endo's '529 Patent Ultimately Would Have Prevailed.

At summary judgment, the parties disputed whether at-risk sales that infringed a valid patent could give rise to purchaser damages; ultimately, the Court did not find Plaintiffs' authority on this point "as persuasive as plaintiffs contend." Order at 6. But for present purposes, whether or not injury from a wrongful at-risk launch is cognizable generally, the facts *here* show that Plaintiffs would not have been better off with an unlawful at-risk launch than they were with the actual settlement.

Here, because Watson would not have been able to launch any earlier than December 2012 due to its manufacturing difficulties, an at-risk launch would have facilitated at most eight months of generic competition before August 2013, which is the point at which (a) all parties' experts agree the Federal Circuit would have ruled, and (b) Defendants contend that any at-risk launch would have been halted as unlawful. The Watson product then would have been forced off the market until patent expiry on October 27, 2015. By contrast, the settlement ensured 25 months of licensed generic competition during the remaining patent term, beginning with licensed entry on September 15, 2013. In other words, the settlement permitted generic sales for a year and a half ***longer*** (25 months versus about 8) than the but-for scenario in which Watson would have launched at risk at the earliest possible date, but then lost the patent litigation at the Federal Circuit. Even Plaintiffs' expert, Mr. Elhauge, conceded this redounds to Plaintiffs' benefit:

> Q: So if a settlement agreement permitted the entrant to be on the market for two years prior to patent expiration, and in a but-for world they would have had 10 months of at risk sales before being forced off the market, and then remained off the market until patent expiration, which of those two scenarios is more procompetitive? . . .
>
> A: So at least assuming a uniform distribution of profits over time, then in that case the settlement is procompetitively having more competition for a longer period than the but-for world would have.

ECF No. 819-31, at 95:6-25. Unless the '529 patent would have been invalidated, the Plaintiffs were not harmed by the timing of the entry of Watson's generic under the settlement.

Other reverse payment cases may not, of course, fit into similar timelines; the point is simply that the timeline matters. Whatever the import of patent validity for cases with different patent expiry timelines, without manufacturing obstacles for the generic, or with faster Federal Circuit horizons, in *this* case the timeline confirms Plaintiffs must prove that the '529 patent would have been invalidated in order to show injury causation.

### D. A "Some Evidence"/"Could Have" Standard of Proof Risks Juror Confusion and Substantial Prejudice to Defendants.

Apart from Plaintiffs' burden of proof, Defendants of course will seek (and the Court has never suggested it would bar the Defendants from seeking) to disprove Plaintiffs' theory as to the likely outcome of the '529 case, by presenting evidence that, more likely than not, Endo would have prevailed. While patent validity here should not be confused for an affirmative defense,[5] a "some evidence"/"could have" standard would leave the jury without a way to address the circumstance where Plaintiffs show some evidence that it was possible Watson was going to win, while Defendants show by a preponderance that it was more likely than not that Watson was going to lose. What if, for example, the jury credits the opinion of Defendants' expert, Professor Schwartz, that Endo was 75% likely to prevail, over Mr. Adelman's projection that Watson was 90% likely to prevail—would it still be instructed that it has "some evidence" that Watson "could have" prevailed? A "some evidence"/"could have" instruction leaves the jury without the tools to weigh the evidence in these scenarios, or, worse, improperly puts the thumb on the scale for Plaintiffs.

[5] *Wellbutrin*, 868 F.3d at 166 ("[i]t is no good saying . . . defendants [] failed to disprove causation").

**E. Granting Reconsideration Will Not Lengthen the Trial.**

The parties have prepared to try this case on the basis that Plaintiffs must prove the likely outcome of the patent case. Plaintiffs certainly never suggested that they would be held only to a "some evidence"/"could have" standard. Rather, they alleged and set out to prove that in the absence of the settlement, Watson *would* have prevailed in the underlying patent litigation, *e.g.*, that "the patents purportedly covering Lidoderm *would not* withstand scrutiny"[6] because they were "invalid."[7] Plaintiffs sought discovery to prove up these points, and intend to call four legal and technical experts to testify at trial on them. Plaintiffs also seek to read for the jury portions of trial testimony from the '529 Litigation, and to admit pleadings, file histories, prior art, and declarations from the underlying case. It was on the basis of these materials that Mr. Adelman opined to a 90% likelihood that the '529 patent would have been invalidated.[8] Requiring Plaintiffs to prove it more likely than not that Watson would have prevailed in invalidating the '529 patent will not prejudice them or lengthen the trial.

**CONCLUSION**

For the foregoing reasons, the Court should rule that Plaintiffs must prove at trial, by a preponderance of the evidence, that Watson would have prevailed in the '529 litigation.

Dated: January 8, 2018

Respectfully submitted,

/s/ *Daniel B. Asimow*

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[6] DPP Compl. at ¶ 119 (emphasis added).

[7] DPP Compl. at ¶ 84; EPP Compl. at ¶ 91; Walgreen Compl. at ¶ 81; GEHA Compl. at ¶ 115.

[8] To whatever extent a "some evidence"/"could have" rule could have lightened Mr. Adelman's load, it will not in fact do so, because Mr. Elhauge still intends to try to use the 90% figure for his calculation of an alternative settlement entry date. ECF No. 925-9, at 61-62.

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**FILER'S ATTESTATION**

I, Daniel B. Asimow, am the ECF user whose identification and password are being used to file Defendants' Motion for Reconsideration Regarding Proof Necessary to Establish Causation. In compliance with Local Rule 5-1(i)(3), I hereby attest that all signatories hereto concur in this filing.

*/s/ Daniel B. Asimow*
DANIEL B. ASIMOW

**CERTIFICATE OF SERVICE**

I, Daniel B. Asimow, hereby certify that on January 8, 2018, I electronically filed the foregoing document(s) using the CM/ECF system, which will send notification of such filing to the e-mail addresses registered in the CM/ECF system.

Executed on January 8, 2018 in San Francisco, California.

*/s/ Daniel B. Asimow*
DANIEL B. ASIMOW